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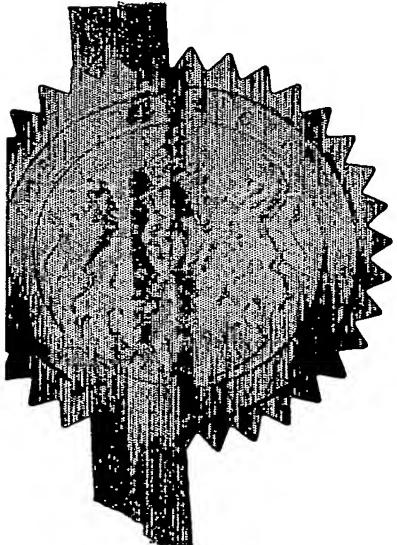
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R. Mahoney

Dated

3 December 2004

1/77
21NOV03 E854029-1 D01147
F01/7700 0.00-0327112.9**Request for grant of a patent**

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21 NOV 2003

 Full name, address and postcode of the or of
 each applicant (*underline all surnames*)

 Clinicial Designs Limited
 The Dower House
 Aldsworth
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Patents ADP number (*if you know it*)8758039001
GB
 If the applicant is a corporate body, give the
 country/state of its incorporation

Title of the invention

Dispenser and Reservoir

Name of your agent (*if you have one*)

NIGEL BROOKS CPA

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ents Form 1/77

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DISPENSER and RESERVOIR

The present invention relates to a dispenser, particularly though not exclusively for dispensing aerosol or powder borne medicaments, and to a source reservoir for such a dispenser.

I have applied for a number of patents on dispensers for a gaseous, gas borne or droplet substance. In particular, in my prior International Patent Application, PCT/GB98/00770, at least as amended on entry in the European Regional Phase, there is described and claimed:

A dispenser for a gaseous, gas borne or droplet substance, the dispenser including:

- a body having a mouthpiece with an inhalation/insufflation orifice at its end;
- a junction in the body for a source of gas or evaporable liquid comprising or containing the said substance (the source being carried by the body); and
- a breath actuatable valve, for controlling the release of said gas or liquid, comprising:
 - a valve inlet connected to the junction;
 - a valve outlet;
- a flexible tube extending from the junction, between the inlet and the outlet, for receiving the said gas or liquid, the tube having a portion which is movable between a closed position in which the tube is kinked for closure of the valve and an open position in which the tube is un-kinked for opening of the valve; and
- a movable member, for moving the movable portion of the tube to control its kinking, and being movably mounted in the body for movement by the act of inhalation from a rest position towards the orifice – or at least in the direction of air flow through the dispenser;
- the tube being kinked to an obturating extent when the movable member is in a rest position and un-kinked when the movable member is moved on inhalation for release of the gas or liquid.

Such a dispenser can loosely be classed as a breath actuated, kink valve dispenser and is referred to herein as "My Earlier Breath Actuated, Kink Valve Dispenser".

5 With such a dispenser, in common with others of my design and other designs, there is advantage to the user in knowing how many doses are left in the reservoir of the substance source, the reservoir typically being an aerosol valve can, the can being an aluminium pressing.

10 Two approaches to dose measurement are known.

Firstly, dispensers actuated by depression of the end of the can towards the body of the dispenser body can be provided with electronic or mechanical counters which sense the number of depressions and count down to indicate exhaustion of the 15 dispenser. This approach is costly.

A second approach is to provide the source with a transparent reservoir, typically of glass. Existing glass reservoirs have replicated the shape of the prior pressed aluminium can. Their shape renders difficult estimation of the number of 20 doses remaining.

The object of the present invention is to provide dispenser having a reservoir whose content can be readily estimate, particularly as it approaches exhaustion.

25 According to one aspect of the invention there is provided a dispenser for a gaseous, gas borne or droplet substance having a source of the substance, the source having a reservoir with:

- a major portion having a comparatively large cross-section of its substance space and
- a minor portion having a comparatively small cross-section of its substance space,

the reservoir being translucent, and preferably transparent, at the minor portion at least, whereby a user can note a comparatively rapid depletion with use of the

quantity of substance remaining when the source approaches exhaustion of the substance.

According to a second aspect of the invention there is provided a source for a
5 dispenser of a gaseous, gas borne or droplet substance from the source, the source
having a reservoir with:

- a major portion having a comparatively large cross-section of its substance space and
- a minor portion having a comparatively small cross-section of its substance space,

10 the reservoir being translucent, and preferably transparent, at the minor portion at least, whereby a user can note a comparatively rapid depletion with use of the quantity of substance remaining when the source approaches exhaustion of the substance.

15 According to a third aspect of the invention there is provided a reservoir for a source of a gaseous, gas borne or droplet substance to be used in a dispenser, the reservoir having:

- a major portion having a comparatively large cross-section of its substance space and
- a minor portion having a comparatively small cross-section of its substance space,

20 the reservoir being translucent, and preferably transparent, at the minor portion at least, whereby a user can note a comparatively rapid depletion with use of the 25 quantity of substance remaining when the source approaches exhaustion of the substance.

The minor portion can have a constant cross-section or a progressively diminishing cross-section, whereby the rate of fall of the level of the substance 30 increases as it is further depleted.

Normally the minor portion will be at the opposite end of the source from its release valve, with the user holding the dispenser valve-up to observe the level of the

substance in the minor portion. However, the minor portion could be provided at the valve end of the reservoir as a diminishing cross-section neck.

The reservoir can be of glass or transparent/translucent plastics material.

- 5 Where it is of glass, this can be enclosed in a plastics material sheath, typically a shrink wrapping or an insert moulding, i.e. a moulding of the plastics material sheath onto the glass reservoir within a mould tool. Where the minor portion is to have a cross-section so small as to be impractical to form in glass, in production with sufficient precision, it is envisaged that the reservoir as such can be provided as a
10 plastics material moulding, possibly enclosed by a robust, impermeable outer enclosure, such as a glass casing, itself enclosed in a shrink wrapping or an insert moulding for instance.

Alternatively, the reservoir can be provided with an insert, which substantially
15 reduces the cross-section thereof, typically at its end distal from the valve. Again, the insert can be at the valve end. In either case the insert can be formed as part of a component of the valve in the source for metering a dose from its reservoir. The insert can be parallel or tapered, the latter shape providing an increasing rate of fall with depletion.

20

To help understanding of the invention, various specific embodiments thereof will now be described by way of example and with reference to the accompanying drawings, in which:

Figure 1 is a side view of a dispenser according to the invention;

25 Figure 2 is a scrap view of the reservoir of the dispenser of Figure 1, inverted and approaching depletion;

Figure 3 is a view similar to Figure 1 of another dispenser of the invention; and

Figure 4 is a similar view of a third dispenser of the invention.

30

Referring to Figure 1, the dispenser 1 has a source 2 of medicament with a transparent reservoir 3 of glass sheathed in a transparent plastics material shrink wrapping 4, which provides an enclosure against explosion of the glass in the event of

accidental breakage of the glass. The reservoir contains not only a liquid medicament 5, but also a gaseous propellant liable to cause the glass to explode if broken.

A valve 6 of the source, shown only in outline in Figure 1, is within a body 7
5 of the dispenser. The valve is attached to the reservoir by a crimped-on aluminium
sleeve 8.

The reservoir is parallel 11 through much of its length, where it has a
comparatively large cross-section of its substance space 12, but has a tapered tip 13
10 remote from the valve 6, where it has a comparatively smaller and decreasing cross-
section.

With the dispenser inverted, Figure 2, the level 14 of the medicament 5 is
within the tapered tip when the medicament is close to being used up. As use of the
15 dispenser continues, the level falls progressively faster, giving the user an indication
that a fresh dispenser will soon be required. Typically the user will take a fresh
dispenser with him when the level is such as to indicate that the daily number of doses
will exhaust the reservoir.

20 Turning to Figure 3, the dispenser 101 there shown has a glass reservoir 103
within a welded-on transparent cover 121, welded at a position appropriate for its
breath actuated, kink valve mechanism, such as disclosed in my patent application
No. PCT/GB03/001102. The reservoir has indentations 122 in the glass which provides
dimples 123 on the inside surface of the reservoir. An opaque plastics material slug
25 124 is pushed past the dimples, to be held by the dimple against an end 125 of the
reservoir. The slug has a rib 126 keeping it centred in the reservoir and a diameter
such that the peripheral space between the slug and the inner wall of the reservoir has
a considerably reduced cross-section in comparison with that of the reservoir where
the slug is not present.

30

As the source approaches exhaustion, the level observed in the reservoir when
inverted drops to be in slug/glass annulus 127. As in the Figure 1 embodiment, this
gives a good indication of impending exhaustion.

Turning now to Figure 4, the dispenser 201 thereshown again has a parallel glass reservoir 203. Within it is a translucent plastics material lining of a shape essentially similar to that of the reservoir 3, i.e. with a tip 213 of lesser cross-section. The exhaustion level can be observed in this also.

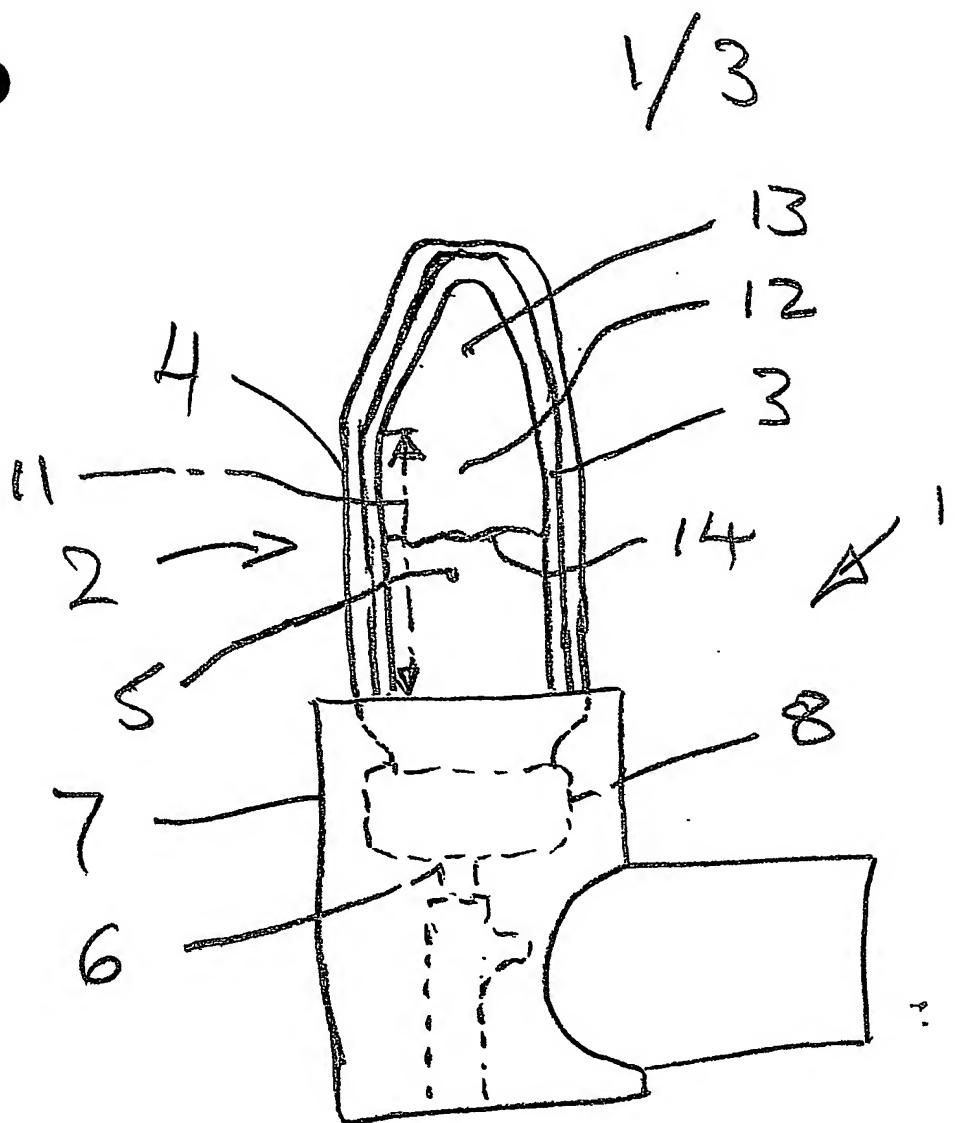


FIGURE 1

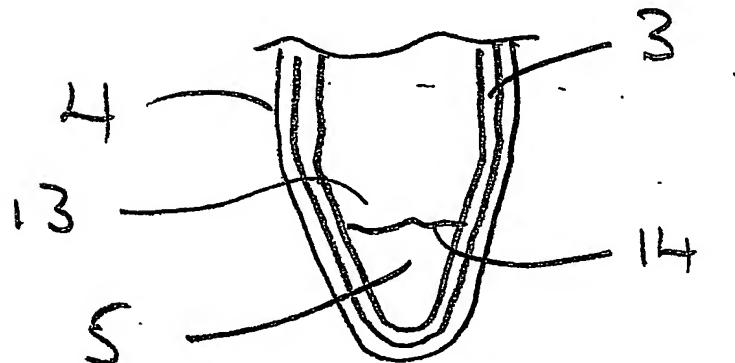


FIGURE 2

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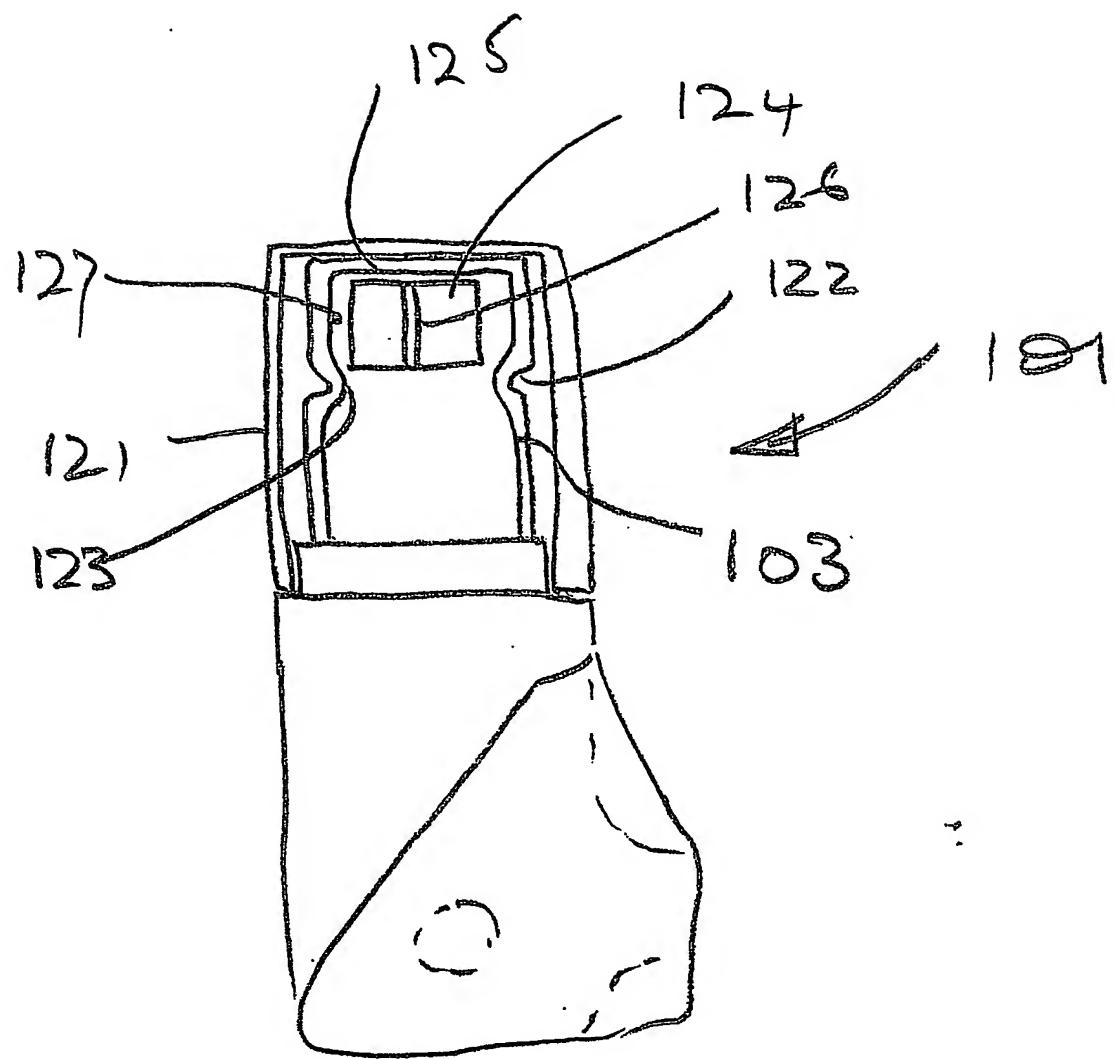


FIGURE 3

3/3

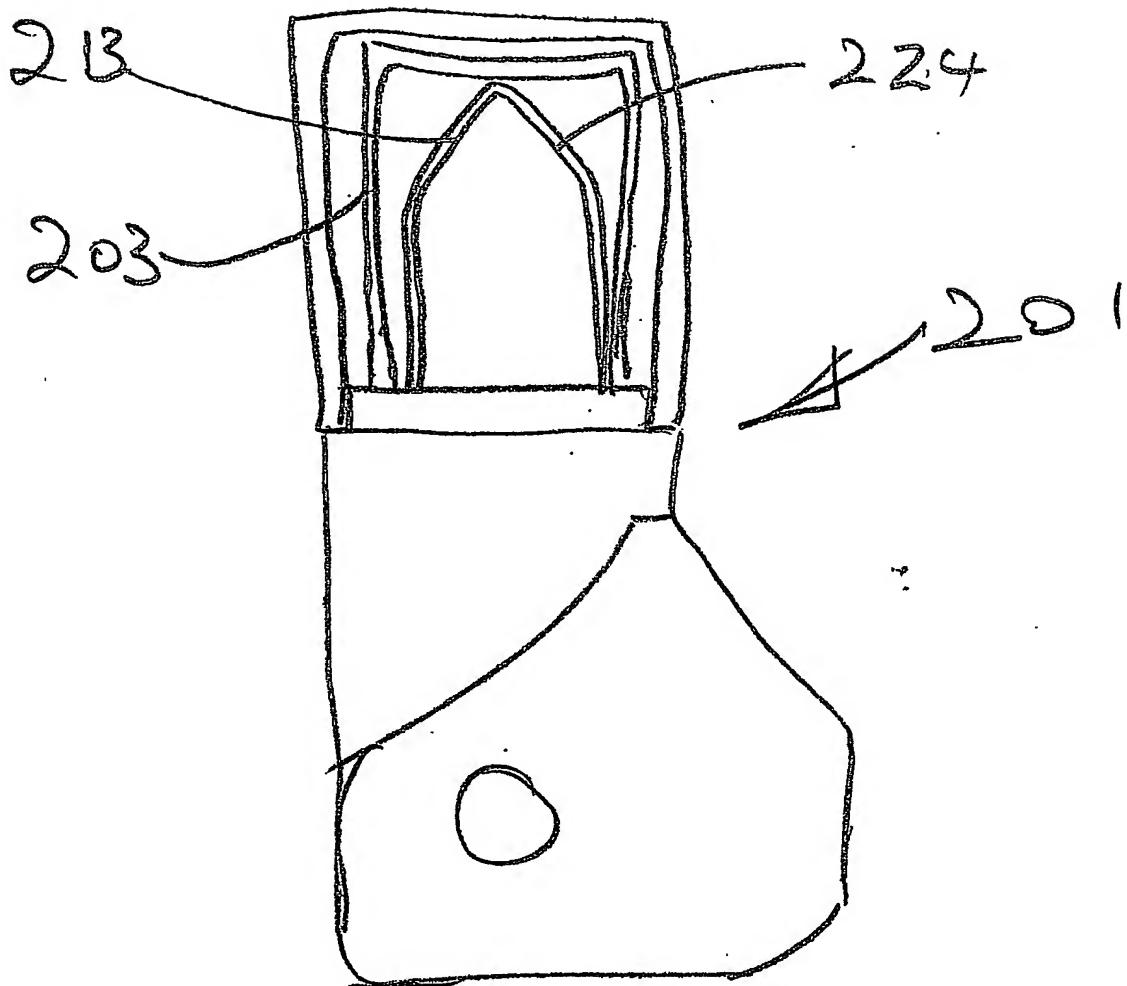


FIGURE 4

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